RESPIRATORY HUMIDIFIER HFNC
NeoHiF

Manual Book

Elitech® TECHNOVISION

Preface

In order to use this series of products correctly and effectively, please read the instructions carefully before using this series.

This series of products is only suitable for the purposes described in this manual.

This series of products is suitable for use in hospitals, long-term care institutions and home.

Be sure to use this therapy device according to your doctor's pres- cription. The patient can use the product as an intended operator.

If this product has been used by multiple patients, it must be cleaned and disinfected in accordance with the requirements of this manual before each patient is used.

The repair of this series of products can only be carried out by trai- ned professional maintenance personnel; do not disassemble the equipment to replace the accessories.

For further assistance, please contact our local representative office. The product has a service life of 5 years from the date of manufactu- re. The date of manufacture can be found on the label attached to the back of the product

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1. Product Overview

1.1 Intended Use and Scope of Application

This product is suitable for patients with spontaneous breathing. It can effectively treat patients by providing a certain flow rate and humidified respiratory airflow. These treatments include humidification, oxygen therapy, endotracheal intubation, and tracheotomy. This product can be used in hospitals, long-term care institutions (such as community hospitals, nursing homes, etc.) and home.
This product cannot be used for life support.

1.2 Contraindication

- Acute sinusitis and otitis mediaO
- Epistaxis.
- Symptoms that may cause inhalation of gastric contents.
- The patient was unable to clear the secretion.
- Hypotension or marked intravascular insufficiency of blood volume.
- Pneumothorax or mediastinal emphysema.
- Craniocerebral trauma or surgery.
- Insufficient respiratory drive.

1.3 Safety Tips

⚠ **WARNING**：

- This device cannot be used for life support.
- This device has no built-in battery. If the power supply is interrupted, the treatment will stop.
- The guidelines in this manual are not a substitute for medical treatment.
- Gas conveyed by this device will produce positive airway pressure effect. Possible adverse reactions to positive airway pressure should be considered in the treatment.
- This device can not be used in magnetic resonance imaging (MRI) or CT examination.
- Do not use consumables that have not been disinfected or have expired, so as not to cause serious harm such as infection.
- If there are any abnormalities in the device, such as abnormal sounds or abnormal air temperature in the tube, odor, parts damage and other undesirable phenomena, please immediately stop using and contact the supplier.
- Do not immerse this device, humidification chambers, or power cord in water or use this device in humid environment. If water is sprinkled on devices or humidification chambers carelessly, disconnect the power supply immediately, let the devices air-dry naturally, and contact the supplier.
- Before cleaning, please disconnect the power supply; ensure that all parts are dry after cleaning before connecting the power supply.
- When connecting the power cord, check whether the power cord is damaged or not. If so, please replace it.
- Do not leave the device or power cord close to any heat source.
- When the device is running, do not carry out any service or maintenance.
- Do not invert or tilt the device with water in the humidification chamber to prevent the water from flowing back into the main device.
- It is not suitable to use this device when the room temperature is over 30 or below 10℃. When the room temperature is lower than 18 or higher than 28℃, the output humidity may be affected.

- Do not reserve the respiratory tube too long in the patient's bed to avoid winding around the patient's head or neck.
- The signal input/output port of this device is only used with function or device designated by our company.
- Unless otherwise specified, please send this device to the authorized maintenance center for inspection and maintenance.
- When using oxygen-enriched gas, the device should be as far away from the fire source as possible.
- When consumables such as heating tube are used longer than the time specified in this manual, they may cause serious injury to patients such as infection.
- If the storage conditions do not meet the requirements of the operating environment, when the device enters the operating state from the storage state, it must be placed in the operating environment for more than 24 hours before use.
- The product cannot be moved while it is in use.

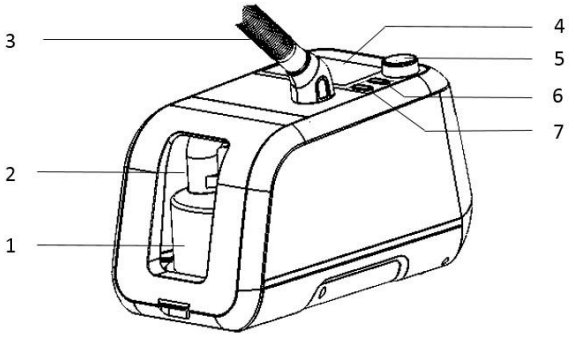
⚠ **ATTENTION**：

- Use of accessories not provided or recommended by our comp- any may reduce the therapeutic effect, cause respiratory burns or damage the device.
- Regularly inspect the device; defective devices and accessories shall not be used. If there are damaged, missing, apparently worn, deformed or contaminated parts, please contact the supplier.
- Use the device away from heating or cooling device (such as exhaust fans, radiators or air conditioners).
- Do not place the device where it is easy to be collided or tripped by the power cord.
- Ensure that the device is clean, dry and ventilated around, and that there is no possibility of blocking breathing tube, air intakes or articles covering the device.
- The device is not suitable for use in an environment where air (or oxygen) is mixed with flammable anesthetics such as nitric oxide. The device should not be used in an environment where flamma- ble gases such as narcotics are present.

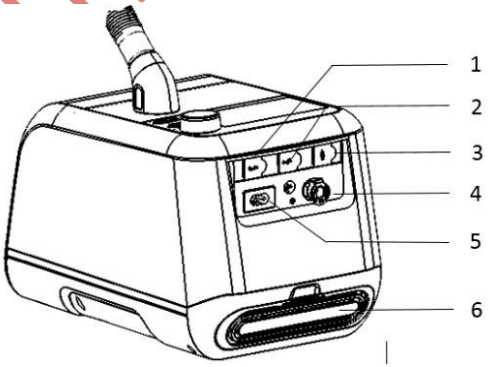
- Do not use the device in the smoke environment, because the smoke of tobacco accumulates in the device, causing abnormal work.
- Before each patient is used, please perform the examination according to the requirements described in this manual to ensure that the alarm sound can be heard normally.
- The intended operator of this device may be the patient or the family of the patient.
- During the use or storage of this device, pets, all kinds of pests and children should be avoided to avoid damage to the device itself or the patient.
- This device automatically stores user setting parameters and monitoring data. External power interruption has no effect on the saved data.
- After the device is powered on or re-powered, the default setting parameter is the user setting parameter before the last stop.
- Nasal delivery of gas produces a positive airway pressure dependent on airflow. Please consider the patient's possible adverse reactions to positive airway pressure before use.
- The maximum output pressure of this device is 100hPa. When the part of the humidification is under the pressure of 6KPa, the leakage rate is less than 10mL/min, and the compliance is less than 10mL/kPa@60cmH2O per meter.
- When the flow setting exceeds the flow recommended by the current patient interface, the output pressure of the device will increase.
- The power-on self-test function of this device will automatically perform software and hardware check. If the power-on self-test fails, do not use this device.
- For the model selection and usage of the patient interface of this device, please refer to the separate instructions and follow the doctor's instructions.
- Do not place the product in a position where it is difficult to disconnect with AC power.
- Do not use non-medical oxygen.

2. Device and Accessories

2.1 Main device



No.	Name	No.	Name
1	Auto-fill chamber	5	Knob
2	Chamber adapter	6	Standby / Treatment key
3	Heating tube	7	Mute key
4	Display screen		



No.	Name	No.	Name
1	SPO2 port	4	O2 inlet
2	Serial port	5	Power connector
3	Nurse call port(NeoHiF)	6	Air Filter

2.2 Accessories

NO.	Description	Applicable target dew point temperature	Applicable Target Flow Velocity
122013562	Heating tube	29 - 37℃	10 – 80L/min
230001341	Auto-fill chamber	29 - 37℃	2 – 80L/min
122013563	Elbow Kit	29 - 37℃	2 – 80L/min
230001277	Nasal Cannula（L）	29- 37℃	10 – 80L/min
230001276	Nasal Cannula（M）	29 - 37℃	10 – 60L/min
230001275	Nasal Cannula（S）	29- 37℃	10 – 50L/min
230001342	Tracheal intubation interface	37℃	10 – 70L/min
210003484	Power cord	----	----
130019823	Air Filter	----	----
122013564	O2 inlet hose	----	----

Note: Depending on different types of device, the accessories may be different. After unpacking, please check the packing list first.

2.3 Symbols

	Standby/Treatment		Mute
	ATTENTION		Pay ATTENTION to high temperature
	BF type device		Please refer to the instructions.
	''Class	IP21	Anti leakage grade
SN	Serial Number	~	AC power supply
	Wastes of electronic components must be collected separately and disposed of in accordance with local laws. It could not be disposed as Municipal waste.		Single-use
CE 0123	93/42/EEC Class IIa		

2.4 Applied parts

Breathing tube and SpO2 module with cable. The product can trans- port the gas into patient's face or nasal, e.g. nasal cannula and trach- eostomy direct connection to patient.

3. Setup

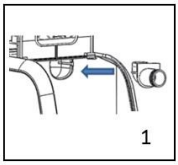
This main device must be placed smoothly on a plane or trolley bel- ow the height of the patient's head. The operator should have easy access to the host and view the device display information. Please keep the distance between the host and the wall at least 5cm. Make sure that the main air intake and vents are not covered by other items, that the air around the unit is ventilated and away from any heating or cooling equipment (such as forced vents, radiators or air conditioners).

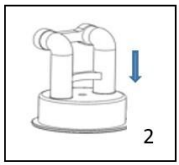
⚠ **WARNING**：

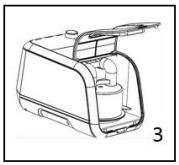
- Connect the chamber and the device before connecting the power supply.
- Do not touch the chamber or heating plate during use.
- If there is water in the chamber, please be careful not to tilt the main device in order to prevent water from flowing into the internal of the main device.
- Increasing the extra temperature above room temperature in any part of the heating tube or patient interface can cause injury, such as covering with quilt, or heating under the heating head of the neonatal incubator or the thermal rescue table.

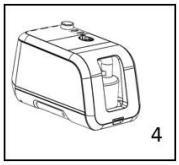
3.1 Installing the chamber

1. Open the cover plate of the main device, push the elbow into the main unit.
2. Remove the plug on the chamber and install the provided connector on the two interfaces of the chamber.
3. Place the chamber on the heating plate gently and push it into the clamping groove of the chamber. **ATTENTION** should be paid to the ventilation port of the main device to ensure that the connection does not leak.
4. Cover the main device cover plate, take out the water pipe and straighten it out.



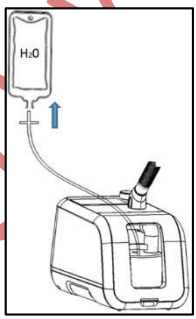






3.2 Conneting the water bag

1. Hang the sterile water bag on the hook so that it is at least 20cm higher than the main machine to ensure that the distilled water in the water bag is sufficient to prevent exhaustion.
2. Insert the conical tip of the water pipe end into the interface at the bottom of the water bag, and open the ventilation cover beside the conical tip.
3. Check that the water in the water bag can automatically flow into the chamber until the MAX water level.

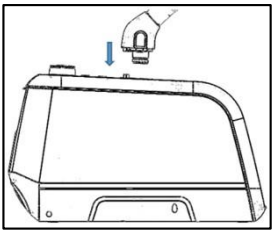


⚠ ATTENTION：

- If the water level of the chamber is higher than the MAX water level, please replace the chamber immediately.

3.3 Connecting the heating tube

1. Insert the heating tube connector gently into the host interface to ensure that the clamp has locked the connector.
2. Hang the heating tube on the hanger to facilitate the next operation.



⚠ ATTENTION：

- Do not let the heating tube touch the skin directly for a long time.
- The heating tube in use should be far away from any electronic monitoring wires (EEG, ECG/EKG, EMG, etc.) in order to reduce the interference of monitoring signals.

3.4 Choose patient interface

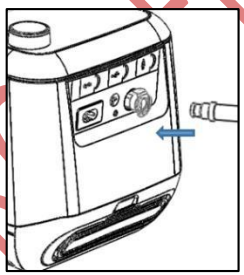
1. Choose the patient interface according to the type of patient and the way of treatment.
2. After removing the package of the patient interface, insert the patient interface connector into the heating tube to ensure that the connection is firm.

⚠ ATTENTION：

- Please do not change the heating tube and patient interface in any way.
- Please use the patient interface provided or specified by our company to avoid burns.

3.5 Oxygent connection

NeoHiF: Connect one end of the oxygen connection tube to the oxygen connector of the main unit, and the other end to the oxygen pressure reducer port or the hospital wall oxygen supply port.



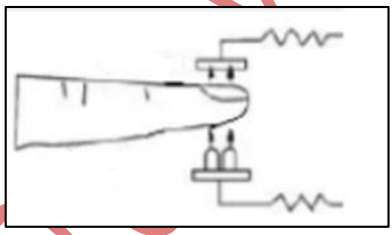
3.6 Connecting SpO2 module

3.6.1 Measuring principle

The SpO2 module is a non-invasive, continuous medical device for detecting arterial oxygen saturation and pulse rate. The principle is based on the spectral characteristics of hemoglobin and oxyhemo- globin in the red and infrared regions, and the empirical formula of data is established using the "Lambert Beer" law. The working prin- ciple of the instrument is to use photoelectric blood oxygen detect- ion technology combined with volumetric pulse tracing technology to illuminate human nails with two

different wavelengths of light (660nm red light and 940nm near-infrared light) by absorbing the perspective finger-type sensor. The component acquires the meas- urement signal, and the acquired information is displayed on the display screen through the electronic circuit and the microprocessor for convenient reading.

It consists of a two-layer component and a photodetector. Bone, cell tissue, pigmentation, and venous blood vessels all have different absorption constants for light. When arteries pulsate with heart con- traction and relaxation, the amount of light absorbed varies with increasing blood flow. The different absorption rates of light when dilating and contracting the heart are converted to measurements of blood oxygen saturation. This measurement is blood oxygen saturation.



SpO_2 module measurement

3.6.2 Connecting Method

- Insert the blood oxygen module into the main device USB interface
- Insert your finger into the rubber hole (the finger is best extended), with the nail facing up.

⚠ ATTENTION：

- When the oximeter is damaged or the communication fails, the display SpO_2 and pulse rate (PR) display the value "--".
- The data update period is 1S.
- Before using this product for testing, please wipe the finger grip rubber with medical alcohol. Wipe the tested fingers with medical alcohol before and after use.
- Since this module does not have an alarm device, this product is not suitable for continuous monitoring of the patient.
- Do not shake your fingers during use. It is best not to be in motion.
- Nail must be upward when the fingers are inserted.
- Prolonged use of excessive pressure of the blood oxygen sensor rubber hole will cause the finger to be overstressed and damaged.

4. Use the Device

4.1 Device Display Guide

The device's user interface allows you to adjust settings and check treatment information. The user interface includes display screen, buttons and knob. The knob is used to select and confirm the sele- cted content.

Adjustment settings:

1. Rotate the knob to the screen displays the menu page you want.
2. Press knob to confirm entering menu page.
3. Rotate knob to change parameter setting;
4. Press knob to save parameter settings.

4.2 Start the Device

Before starting the device, please check and confirm that the device and accessories are in good condition, and the power cord and ace- ssories are connected correctly. After the AC power supply is connec- ted, the device starts, the screen displays the boot screen, and the internal self-check is automatically performed.

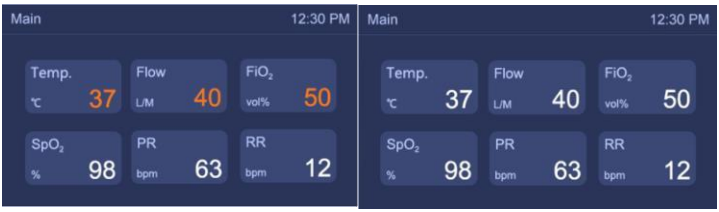
4.3 Flow Mode Selection

- **Low flow mode:** temperature range 29 - 34℃; Flow setting range 2 - 25L / min, increase / decrease 1 L / min each time.
- **High-flow mode:** temperature range 29-37℃; Flow range 10-80 L/min, increase/decrease 1 L/min each time (flow rate less than 25L/min,) or 5 L/min each time (flow rate higher than 25L/min).

4.4 Preheating and treatment

After the flow mode selection is completed, the device will automa- tically enter the system to preheat according to the last set parame- ters. In the preheating process of the system, the flow rate, temper- ature and FiO_2 of the main interface is in orange colour.

After preheating, the flow rate, temperature and FiO_2 of the main interface show that the font color and font color all turn white. At this time, please install patient interface, connect patients and start treatment.



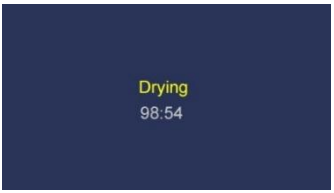
ATTENTION：

- In the preheating stage, when the initial ambient temperature is 23±2℃, the gas outlet temperature at the patient's end can re- ach 29℃ in 10 minutes and 37℃ in 30 minutes.
- If the patient is using the device for the first time, he will feel the inhaled air is hot. Please continue to breathe normally. If the pat- ient suffers from heat intolerance, please follow the doctor's ins- tructions to lower the treatment temperature.
- Low temperature environment may cause the device to fail to reach the set target temperature. Please consider reducing target flow settings.
- In high flow mode, the setting range is 29 - 37 ℃ when the flow rate is 10 - 60L/min; the setting range is 29 - 34 ℃ when the flow rate is 65 - 80L/min.

4.5 End of Treatment

After treatment, disconnect the device from patient. If there is a little water in the tube, please raise the patient's end so that the water flow back to the chamber. Users can choose "Tube drying mode" or shut down directly (this is not recommended).

- **Tube drying mode:** Press and hold for 3 seconds. The device automatically enters the tube "**Drying**" mode (it takes 99 minutes) to dry the tube for the next use. When this mode is finished, the device will shut down automatically.



- **Shutdown:** Press and hold it for 6 seconds. The device will shut down automatically.

ATTENTION：

- Power failure or direct disconnection of the power cord during therapy will lead to "power failure alarm". Please press the "mute"

button to eliminate the alarm.

- After the treatment, if there is water in the pipeline, raise one end of the breathing tube to return the water to the humidificat- ion tank.

4.6 Menu Navigation

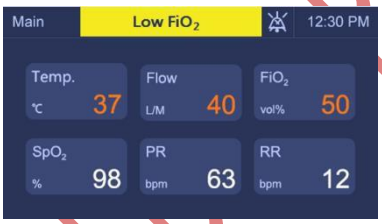
After flow mode selection is completed, the user can select the following menu options by rotating the knob:

⟺ Main menu ⟺ Trend ⟺ Log ⟺ My Setting ⟺ Device Info ⟺ Service ⟺

4.6.1 Main menu

Parameter settings:

On the main menu, press the knob and enter the parameter setting page. Users can set the flow rate, temperature and FiO2 in turn.



⚠ ATTENTION：

- The screen will directly return to the simplest mode of the main menu if there is no operation within 40S. The simplest mode will shield the information prompt area and only display the parame- ter monitoring value.
- If an alarm occurs in the simplest mode, the screen will return to the normal mode of the main menu.
- Respiratory frequency monitoring is used for patients with peak inspiratory flow greater than 18 L/min. Inspiratory peak flow in undersized patients may result in inaccurate monitoring of respi- reatory rate.

4.6.2 Trend

When you select , the following options will be displayed:

Option	Description
Meas.(Measure)	Press the knob to measure the number of points on the trend map, and press the knob again to exit
Day1(Trend review time span)	Retrospective review of treatment trends for the last 1, 3 or 7 days

Config	Simultaneous trend data display of two arbitrary aarameters in Configurable Options
Clear	Clear the trend data before the current time
Back	Return to Trend map selection menu

4.6.3 Log

When choosing the log menu  , the setting of parameters, prompt information and alarm information of the device during the working period will be displayed in chronological order. Through the knob, you can turn the page and press the knob to return to the log menu page.

4.6.4 My Setting

When you select my settings menu  , the following options will be displayed:

Option	**Description**
Font size	Can be set to small, standard or large fonts
Backlight	Levels 1, 2, 3 and automation can be set. Level 3 screen has the highest brightness. When set to automatic, the backlight is automatically turned off after 3 minutes without operation.
Date and Time	Current date and time can be set
Language	Language for device display and alarm settings
Voice	ON/OFF
Chamber/ tube reminder	Can be set to OFF, 7 days, 14 days, 30 days
Patient interface reminder	Can be set to OFF, 7 days, 14 days, 30 days
Filter reminder	Can be set to OFF, 1000 hours, 1500 hours
SpO_2	ON/OFF
Back	Return to My Settings menu page

4.6.5 Device Info.

When you select the device information menu, the following options will be displayed:

Option	Description
Software Version	Display the comprehensive version number of the software in the current device
Therapy time	Display the therapy time
Turbine working hours	Display the total working hours of the turbine in the device
chamber/tube hours	Display the use time of chamber/heating tube. It can be reset
Patient interface hours	Display the time of the patient's interface. It can be reset
Filter hours	Display the use time of air filter. It can be reset.
Device configuration	Display current device configuration code
Back	Return to the Device Information menu page

4.6.6 Service

When you select the system maintenance menu, the following options will be displayed:

Option	Description
Calibration	Calibrate flow sensor, pressure sensor and FiO_2 sensor. Entry by password after authorization.
Settings	Used for system upgrade and zero treatment time.
Back	Return to the System Maintenance menu page

4.7 FiO_2 adjustment

Please adjust the FiO_2 setting directly through the FiO_2 setting option in the parameter adjustment menu, and the device will automatically output the FiO_2 according to the setting requirements

⚠ ATTENTION：

- Oxygen flow setting should be titrated according to patient oxygen saturation level
- FiO_2 and oxygen flow should be set in accordance with doctor's prescription.
- Please check in time whether the blood oxygen saturation has reached the appropriate level under the prescribed flow rate.
- For patients whose oxygen saturation is significantly decreased due to oxygen interruption, FiO_2 should be monitored continuously.
- Oxygen must be used away from the source of fire. The device should be placed in a well ventilated environment.
- Oxygen device must be kept away from oils or fats in order to avoid fire.
- After treatment, please close the oxygen source and disconnect the oxygen tube from the device.

Quick Settings for Oxygen Concentration

Oxygen Concentration (%)		Input pure oxygen flow rate (L/min)								
		10	15	20	25	30	35	40	45	50
Setting flow rate of humidifier (L/min)	10	100%								
	15	73%	100%							
	20	61%	80%	100%						
	25	53%	68%	84%	100%					
	30	47%	61%	74%	87%	100%				
	35	44%	55%	66%	77%	89%	100%			
	40	41%	51%	61%	70%	80%	90%	100%		
	45	39%	47%	56%	65%	74%	82%	91%	100%	
	50	37%	45%	53%	61%	68%	76%	84%	92%	100%
	55	35%	43%	50%	57%	64%	71%	78%	86%	93%
	60	34%	41%	47%	54%	61%	67%	74%	80%	87%
	65	33%	39%	45%	51%	57%	64%	70%	76%	82%
	70	32%	38%	44%	49%	55%	61%	66%	72%	77%
	75	32%	37%	42%	47%	53%	58%	63%	68%	74%
	80	31%	36%	41%	46%	51%	56%	61%	65%	70%

Note: Gas source pressure is 0.4 MPa.

4.8 Standby

Press ⏻ to enter the standby state during the treatment of the device. In standby state, the heating plate of the device will stop heating until the

device exits standby state and re-enters preheating. In standby state, the device will continue to output flow until the tank temperature is reduced to a reasonable level, flow output aut- omatically stops.

5. Alarms

The device alarm is divided into alarm information and prompt information. All alarms are intermediate alarms. The alarm can be operated by voice, screen color display, screen text prompt and voice prompt. When the alarm occurs, the Yellow bottom alarm content will appear in the alarm area of the main interface. Alarm voice users can choose "beep" or voice alarm.

When the device is in the alarm, press  and the alarm sound will be muted for 115seconds. When the mute time is over or a new alarm appears, the alarm sound will be turned on again.

The following table lists the alarm items from high priority to low priority, their meanings and solutions. The device will sort the alarm priority in the device. If multiple alarm conditions occur at the same time, the device will display the highest priority alarm

Alarms	**Meanings and Solutions**
System fault	The device detects internal failures. Alarm within 5seconds. Restart the device. If the failure persists, please write down the failure code and contact the local representative office.
Check tube	No heating tube was detected. The heating tube may be damaged or incorrectly inserted. Alarm within 2 minutes. Check and make sure that the heating tube is not damaged. Insert again. If the alarm still exists, please replace the new heating tube.
Check for leaks	Device inspection found that there was leakage in the system. The chamber may not be installed in place. Alarm within 10 seconds. Check and ensure that the chamber is installed in place and there is no leakage at the interface.

Alarms	Meanings and Solutions
Check for blockages	Device inspection found that the system was blocked. The heating tube or patient interface may be blocked. Alarm within 15seconds. Check whether the heating tube or the patient's interface is blocked.
Low FiO_2	Device monitoring value is less than the set value minus 6% of full range and lasts for 30 seconds. Alarm within 1 minutes. Check that the oxygen source is connected correctly. Check the pressure of oxygen source and adjust the flow rate of oxygen according to need. Modify FiO_2 settings to current monitoring values.
High FiO_2	The device monitoring value is more than the set value plus 6% of full range and lasts for 30 seconds. Alarm within 20 seconds. Check the pressure of oxygen source and adjust the flow rate of oxygen according to need. Modify FiO_2 settings to current monitoring values.
Check water	The water in the chamber is exhausted. The water in the water bag may be exhausted or the chamber may fail. Alarm within 40 minutes. Replace the water bag. Replace the chamber.
Not reach target temp.	Failure to reach the target set temperature. It is possible that the device will be used at a lower ambient temperature. Alarm within 30 minutes Raise the ambient temperature. Reduce target flow rate.
SpO_2 /Comm. failure	SpO_2 sensor failure. Probe may not be connected or circuit failure. Alarm within 20 seconds. Check and re-insert the SpO_2 probe. Replace the probe.

Power out	The external power supply of the device is disconnected during operation. It may be an external power failure or a disconnection of the power cord. Alarm within 5seconds. Check the external power supply. Re-insert the power cord into the power supply.

ATTENTION：

Before each use, please pull off heating tube and power cord in turn to confirm that the alarm can be heard by operator and function of the device is normal.

6. Cleaning and Maintenance

Cleaning and maintenance of device can ensure better treatment quality. Cleaning and disinfection must be performed before use between different patients. After each use, it should be cleaned and disinfected as soon as possible. When touching or disassembling the device and its accessories, please strictly follow aseptic operating procedures to minimize pollution. It is recommended to wear prot- ecttive gloves to avoid infection.

6.1 Split parts

1. Shut down and disconnect the device power supply.
2. Turn off the source of oxygen supply end, remove oxygen pipe and other external devices (such as oxygen connector, SpO2 probe or atomization probe).
3. Remove the heating tube from the main air supply port.
4. Separate the patient's interface from the heating tube.
5. Open the cover and remove the chamber.
6. Remove the chamber adapter between the chamber and the main device and pour out the remaining water.
7. Split the main device air supply elbow as shown below

⚠ ATTENTION：

- Make sure the chamber is not hot before removing it.
- Do not disassemble the parts forcefully.

6.2 Cleaning and disinfection

To avoid cross-infection, please use the new accessories (nassal canula, heating tube, chamber adapter, elbow kit and humidification chamber) for the next patient. The main unit should be cleaned. Failure to follow the cleaning, disinfection and periodic replacement of accessories may result in infection of the patient.

6.2.1 Cleaning and disinfection methods in hospital

1. Shut down and power off, disconnect all external connections, and split the parts according to 6.1.
2. Safely dispose of the chamber, chamber adapter, elbow kit and heating tube in accordance with medical waste regulations.
3. Use a disposable damp cloth to remove neutral detergent, 70% alcohol or 70% alcohol wipes to clean the main unit. Be sure to remove all debris, such as blood and mucus, attached to the surface of the main unit. For stains that are difficult to remove, first wipe them with a damp cloth with a neutral detergent. After removing the dirt, use an alcohol wipe to complete the subsequent cleaning.
4. Complete the disinfected for next use.

6.2.2 Cleaning and disinfection methods at home

6.2.2.1 Daily Cleaning and disinfection

1. After each use, rinse the patient's interface with drinking water and reconnect to the heating tube. Run "Tube drying mode"until it finishes, disconnect the power cord for the next use.
2. Remove the chamber and water bag and dispose of the medical waste in accordance with the provisions of this manual.

6.2.2.2 Weekly cleaning and disinfection

1. Shut down and turn off the power. Disassemble the parts according to the instruction of 6.1 in this manual.
2. Use clean, velvetless textiles and mild tableware detergents to clean the heating tube and the outside surface thoroughly and dry in the air.
3. Reassemble the device for next use.

⚠ WARNING：

- After disinfection, if any parts are damaged or deformed, replace the

damaged parts in time.

- In order to avoid moisture entering into the device and affecting the work of the main device, only after the device, the chamber shell and the tube are completely dried, can the power supply be connected for use.
- Accessories that exceed the accessory replacement cycle should not be used after cleaning and disinfection.

6.3 Accessories replacement period

Be sure to replace the accessories regularly to prevent infection. If the attachment is found to be damaged or discolored during use, replace it immediately. The maximum period of use defined in the table below is limited to a single patient. After replacing the patient, be sure to clean and disinfect as required by this manual.

Item number	Description	Replacement period
230001275	Nasal cannulas (S)	7 days
230001276	Nasal cannulas (M)	7 days
230001277	Nasal cannulas (L)	7 days
230001342	Tracheal intubation interface	7 days
122013562	Heating tube	7 days
230001341	Auto-fill chamber	7 days
130019823	Air filter	3months or 1000hours or as needed
122013563	Elbow kit	7 days

6.4 Replace air filter

1. Disconnect the power supply of the device.
2. Press the upper part of the air inlet cover plate and remove the filter cover from the back of the main device. Remove the old filter element.
3. Pack the new filter element into the filter cover.
4. Re-install the filter cover.

⚠ ATTENTION：

- If the environmental dust and salt fog are heavy, please shorten the replacement period according to the specific situation.

- In order to ensure the effectiveness of treatment, please use the air filter provided by HEYER medical.

6.5 Maintenance and waste disposal

6.5.1 Common failures and solutions

Failures	Possible reasons	Solutions
Screen is off, no air output	Power plug is not connected properly.	Check the power supply.
Tube is not heating	Tube is not connected properly. Tube is damaged.	Re-insert the tube. Replace the tube.
Chamber can't automatically add water	Water bag air intake not opened. Folding and clogging of water pipe in water bag. Chamber float damaged.	Open the air intake of the water bag. Re-straighten out water bags and tanks. Replacement of chamber.

⚠ ATTENTION：

- In case of abnormal operation or malfunction of the device, please contact the supplier for maintenance. Only authorized personnel can carry out maintenance.
- Do not open the casing of the device. In case of damage or malfunction, please contact the supplier immediately.
- This device does not contain repairable parts.

6.5.2 Waste disposal

The device and packaging materials at the end of service life are disposed of according to the relevant laws and regulations of the Country, Or send the end-of-service device, cardboard for packaging and protective plastics to the recycling agency which should have the ability to dispose of plastics, metal parts, printed circuit boards, cables and wires, heating boards for chambers and motors, etc. or to the local representative office of the company. Consumables could be put in the garbage bag.

Hospitals should deal with the device according to the local standard sewage treatment process.

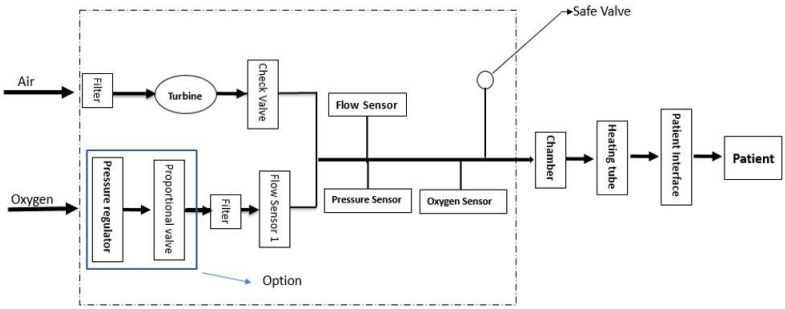
7. Technical Information

7.1 Specification

Items		Specification
Physical property	Dimensions	320mm × 178mm × 193mm
	Weight	3kg
	Chamber capacity	≥100ml
	Tube	Length: 1.8 m ±0.18 m
Electrical properties	Power	100-240 VAC, 50 /60 Hz, 2.5A Max
	Safty Type	Class II, BF
Waterproof level		IP21
Noise		When flow is 80L/min, the A-weighted sound pressure level of noise is not more than 45 dB
Chamber performance	Temperature regulation range	NeoHiF: 29-37℃，step 1℃
Chamber performance	Air temperature at patient junction	≤43℃
	Humidifying capacity	Target temperature is 29 - 36℃, the humidity is higher than 12 mg/L. Target temperature is 37℃, the humidity is higher than 33 mg/L.
	Heating plate power	≤160W
Regulating range of FiO_2		21%-100%
Flow regulation range		In low flow mode, setting range: 2 L / min - 25L / min
		In high flow mode, setting range: 10 L / min - 80L / min

Preheating time		23 ° C, flow 35 L / min, delivery gas temperature reaches 29 ° C in 10 minuts, and reaches 37 ° C in 30 minutes.
Accuracy of oxygen sensor		The monitoring accuracy is ± (2.5% volume percentage + 2.5% gas concentration).
SpO_2 Monitoring		Monitoring range 35 - 100%, monitoring accuracy is ±2% of reading when ≥70%, less than 70% undefined
PR Monitoring		Monitoring range 30 - 240 PR/min, monitoring accuracy ±3 PR/min or ±2%, take the maximum
RR Monitoring		Monitoring range 4 - 45 BPM, monitoring accuracy ± 15% or ± 4 times / min, take the maximum
Normal Work	Temperature	18℃ ~ 28℃
	Humidity	10% RH - 95% RH
	Atmospheric	700 hPa-1060 hPa
Transportation and storage	Temperature	-10℃ ~ +60℃
	Humidity	10% RH - 95% RH
	Atmospheric Pressure	700 hPa-1060 hPa

7.2 Principle



7.3 EMC Statement

The essential performance is to provide user the continuous flow. The customer or the user of the NeoHiF should assure that it is used in such an environment specified by table 1, table 2, table4 and table 9, otherwise, could result in the NeoHiF device improper operation.If you believe your unit is affected by locating it closer to another device, simply separate the devices to remove the condition.

NeoHiF has been designed to meet EMC standards throughout its Service Life without additional maintenance. There is always an opportunity to relocate your NeoHiF within an environment that contains other devices with their own unknown EMC behavior.

⚠ WARNING：

- Use of the NeoHiF adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, NeoHiF and the other equipment should be observed to verify that they are operating normally.
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer could result in increased electromagnetic emissions or decreased electromagnetic immunity of the NeoHiF and result in imp- roper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the NeoHiF, including cables specified by the manufacturer. Otherwise, deg- radation of the performance of this equipment could result.

- If you suspect that the pressure and/or flow rate accuracy is affected by EMC interference remove power and relocate the device to another area. If performance continues to be affected discontinue use and contact your provider.
- NeoHiF is designed to capture the SpO2 the accuracy speci- fication described in the sensor manufacturer's instructions for use. If you suspect that your unit is affected by EMC interference remove power and relocate the device to another area. If perfo- rmance continues to be affected discontinue use and contact your provider.

Table 1

Guidance and MANUFACTURER'S declaration – ELECTROMAGNETIC EMISSIONS	
The NeoHiF is intended for use in the electromagnetic environment specified below. The customer or the user of the NeoHiF should assure that it is used in such an environment.	
Emissions test	Compliance
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class B
Harmonic emissions IEC 61000-3-2	Class A
Voltage fluctuations/flicker emissions IEC 61000-3-3	Comply

Table 2

Guidance and manufacturer's declaration – electromagnetic immunity		
The NeoHiF is intended for use in the electromagnetic enviro- nment specified below. The customer or the user of the NeoHiF should assure that it is used in such an environment.		
IMMUNITY test	IEC 60601 test level	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	± 8kV contact ± 15kV air	± 8 kV contact ± 15 kV air

Electrical fast transient/burst IEC 61000-4-4	±2kV for power supply lines ± 1kV for input/output lines	± 2 kV for power supply lines not comply
Surge IEC 61000-4-5	± 1kV line(s) to line(s) ± 2kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % UT(>95 % dip in UT) for 0,5 cycle 40 % UT(60 % dip in UT) for 5 cycles 70 % UT(30 % dip in UT) for 25 cycles <5 % UT(>95 % dip in UT) for 5s	<5 % UT(>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT)for 5 cycles 70 % UT(30 % dip in UT)for 25 cycles <5 % UT(>95 % dip in UT)for 5s
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m

Table 4

Guidance and manufacturer's declaration – electromagnetic immunity		
The NeoHiF is intended for use in the electromagnetic environment specified below. The customer or the user of the NeoHiF should assure that it is used in such an environment.		
IMMUNITY test	IEC 60601 test level	Compliance level
Conducted RF IEC 61000-4-6	3 Vrms 6 Vrms 150 kHz to 80 MHz ISM bands between 150 kHz to 80 MHz	3 Vrms 6 Vrms
Radiated RF IEC 61000-4-3	3V/m, 80 MHz to 2700MHz; 27 V/m,385MHz; 28 V/m,400MHz; 9V/m,710MHz; 9V/m,745MHz; 9V/m,780MHz; 28V/m,810MHz; 28V/m,870MHz; 28V/m,930MHz; 28V/m,1720MHz; 28V/m,1845MHz; 28V/m,1970MHz; 28V/m,2450MHz; 9V/m,5240MHz; 9V/m,5500MHz; 9V/m,5785MHz;	3V/m 9V/m 27 V/m 28 V/m

Guidance and manufacturer's declaration – electromagnetic immunity
NOTE These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
a: Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device. b: Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.

Table 9 – Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Test frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation [b]	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
385	380 –390	TETRA 400	Pulse modulation [b] 18 Hz	1,8	0,3	27
450	430 – 470	GMRS 460, FRS 460	FM [c] ± 5 kHz deviation 1 kHz sine	2	0,3	28
710	704 – 787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	0,2	0,3	9
745						
780						
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	2	0,3	28
870						
930						
1 720	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217 Hz	2	0,3	28
1 845						
1 970						
2 450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	2	0,3	28
5 240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	0,2	0,3	9
5 500						
5 785						

NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

[a] For some services, only the uplink frequencies are included.

[b] The carrier shall be modulated using a 50 % duty cycle square wave signal.

[c] As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

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